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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/600,022

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Brent C. Gerberding

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EXAMINER

GANESAN, SUBA

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/600,022	Applicant(s) GERBERDING ET AL.	
	Examiner SUBA GANESAN	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 21-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 32-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/24/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 2/12/2010 have been fully considered but they are not persuasive. Applicant argues that Edwin teaches away from direct placement of radiopaque markers on a connector strut of a stent. This is not persuasive because Wolff and Ventura were relied upon as teachings for direct radiopaque marker placement. However, in order to fully and clearly address the claims, Examiner has modified the rejection such that Edwin is only relied upon for the specific teaching of radiopaque marker placement that identifies the ends of a PTFE covering (as such, Edwin's discussion about direct placement of the radiopaque marker on the stent has no bearing on the applied rejection). A reference to Cottone, Jr. (5,824,043) has been added to teach expanded PTFE coverings on a stent body.
2. Applicant's claim amendment including that the radiopaque marker is directly and only attached to the linear connector strut is not described in the specification to a degree to show possession of the invention at the time of filing. Examiner suggests including language such as "embedded" and "crimped" to describe the attachment means consistent with the scope of the specification. It is further not clear that the specification describes radiopaque markers located *only* at the connector struts.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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2. Claims **1-20** and **32-36** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to describe a radiopaque marker attached “directly and only” to the connector strut. It appears that applicant’s device includes connection or attachment to the PTFE covers in addition to the stent connector struts. Furthermore, the specification is silent as to the lack of radiopaque markers at other locations along the stent.

Claim Rejections - 35 USC § 103

1. Claims **1-2, 9-11, 15-17, 20, and 32-36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff (5,104,404) in view of Cottone, Jr. (5,824,043).

2. Wolff discloses a stent structure with radiopaque connector struts 14 that connect adjacent axially aligned oppositely pointing apices (fig. 1-3 and related descriptions). The radiopaque marker is directly attached to the connector 14 (the connector 14 can be either made of radiopaque material or coated with radiopaque material).

3. However, Wolff does not teach the use of an inner and outer covering of PTFE. Cottone, Jr. teaches the use of an outer and inner covering of expanded PTFE for the purpose of addressing vascular dissections, aneurysms, or malformations, including minimizing the risk of developing intimal hyperplasia. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have

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provided the radiopaque stent of Wolff with the expanded PTFE covering as taught by Cottone, Jr. for the purpose of addressing vascular aneurysms and other conditions with a partial graft covering on the stent of Wolff. The combination of Wolff and Cottone, Jr. would be the result of a combination of prior art components, which could have been made with known methods and would have yielded predictable results.

4. The use of stents for correcting cerebral vasculature is known in the art. If not inherent in Wolff and Cottone, Jr., (Wolff is silent as to the dimension of the stent, and the disclosed stent is capable of being placed into a cranial vessel of any animal including rabbits, primates and elephants) to employ a stent to correct aneurysm would have been obvious to one with ordinary skill in the art based on medical considerations.

5. The radiopaque marker of Wolff does not protrude beyond the outer or inner surface of the stent. Cottone, Jr. teaches a graft that does not cover the entire stent. The adhesion method employed by Cottone, Jr. is considered lamination.

6. Claims **3-6**, and **8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff (5,104,404) in view of Cottone, Jr. (5,824,043) as applied above, further in view of Ventura (2004/0044399).

7. Wolff in combination with Cottone, Jr. is explained supra. However, the combination lacks a radiopaque marker in the form of a band that is wound, crimped, or embedded on the stent. Ventura teaches radiopaque marker placement specifically on a connector strut (fig. 4B-C, for example), including a wound band that is embedded into the stent body (fig. 4C).

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8. With respect to claim 5, crimping is considered an obvious means of attaching a radiopaque marker to a stent body. This attachment means would have been obvious to one of ordinary skill in the art as a suitable alternative means of adding radiopaque markers to a stent body. With respect to claim 8, the radiopaque marker 20 can be considered a plug; the limitation "which is inserted into an opening in the stent framework" is a product-by-process limitation, and therefore is not given patentable weight in the absence of distinguishing structure.

9. Claims **7, 12-14, 18, and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff (5,104,404) in view of Cottone, Jr. (5824043), as applied above, further in view of Edwin (2002/0095205).

10. Wolff in view of Cottone, Jr. is explained supra. However, the combination lacks specific teaching for a radiopaque marker located adjacent an uncovered region of the stent, such that the marker indicates the ends of the PTFE covering. Edwin teaches the specific placement of radiopaque markers to identify the ends of a PTFE covering that does not encapsulate the entire stent (the covering is located in the middle of the prosthetic, fig. 5). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the stent graft combination of Wolff and Cottone, Jr., with radiopaque marker placement as suggested by Edwin, such that the ends of the PTFE covering of Cottone, Jr. are clearly identified. Identification of the ends of the PTFE covering would assist the surgeon in addressing aneurysms and other conditions in which the PTFE covering serves a therapeutic purpose.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./
Examiner, Art Unit 3774

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738